

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

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: **Hon. Robert B. Kugler**  
:  
: **Civil No. 1:19-md-2875-RBK-JS**

**This Document Relates to:**

*All Actions*

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**AUROBINDO PHARMA LTD.'S REPLY BRIEF SUPPORTING ITS MOTION FOR  
PROTECTIVE ORDER REGARDING THE DEPOSITION OF DR. RAM MOHAN RAO  
AND PRODUCTION OF HIS CUSTODIAL FILE**

Defendant Aurobindo Pharma Ltd. (hereinafter referred to as “Aurobindo”) by and through its undersigned counsel, hereby submits this Reply Brief in Support of its Motion for Protective Order to preclude the deposition of its Chief Quality Officer Dr. Ram Mohan Rao and the production of his custodial file and in support thereof states as follows:

**I. FACTUAL BACKGROUND**

As mentioned in both Aurobindo’s initial Brief and Plaintiffs’ Opposition, before Aurobindo Pharma Ltd. was served in this action, Plaintiffs asked Aurobindo Pharma USA, Inc. and Aurolife Pharma, LLC (collectively “the U.S. entities”) if they would agree to include Dr. Rao as a custodian. The U.S. entities refused and informed Plaintiffs that Dr. Rao is employed with Aurobindo Pharma Ltd. Despite Plaintiffs’ claims of the importance of Dr. Rao’s testimony and custodial file, they did not bring him up again until their Position Statement dated March 9, 2021. Plaintiffs are now trying to justify their untimely and improper demand for Dr. Rao’s deposition and file, even though they neglected to request it at any time during the past 9 months when they had ample opportunities to do so. Plaintiffs have not explained why they did not respond to

Aurobindo's list of proposed custodians in August 2020, why they did not raise Dr. Rao when counsel met and conferred in January and February of 2021, or why they chose not to include Dr. Rao among the 19 other custodians they asked the Court to order Aurobindo to produce in their Position Statement filed on February 23, 2021. [See Dkt. 967 at pp. 7-10.]

At the February Case Management Conference, this Court approved Plaintiffs' request for Aurobindo to produce additional custodial files to cover the following topics relating to Lantech:

1. Contracting with Lantech;
2. Conducting due diligence on Lantech in terms of quality and cGMP compliance;
3. Providing Lantech with specifications for the use, recovery, recycling, and cleaning of the solvents used in the manufacture of Aurobindo's VCDs; and
4. Investigating any cGMP, contamination, or NDMA issues with Lantech.

In their Response in Opposition to Aurobindo's Motion for Protective Order, Plaintiffs claim that “[b]ased on all the information available to [them], Dr. Rao appears to be the best person to address topic 4 on this list.” However, despite this assertion, Plaintiffs failed to provide any legitimate reason they believe this to be the case. None of the 12 documents attached as Exhibits to Plaintiffs' Opposition make any mention of Aurobindo's dealings with Lantech. Other than the conclusory statement that Dr. Rao is the “best person” to address that topic, Plaintiffs do not provide any evidence that Dr. Rao was directly involved with or has any unique knowledge regarding the investigation of any cGMP, contamination, or NDMA issues with Lantech or any issues regarding Lantech at all. Rather, they focus on Dr. Rao's knowledge of valsartan, quality issues, and the recall generally and fail to show that even that knowledge is superior or unique and unable to be obtained through other means.

## **II. LEGAL STANDARD**

Federal Rule of Civil Procedure 26 requires courts to limit discovery otherwise allowed by the rules if it determines that “the discovery sought is unreasonably cumulative or duplicative, or

can be obtained from some other source that is more convenient, less burdensome, or less expensive.” F.R.C.P. 26(b)(2)(C)(i). This Rule permits courts to prohibit the depositions of certain “apex” witnesses unless (i) the high-level official has personal or superior unique knowledge of the facts alleged and (ii) the information cannot be obtained from lower level employees or through less burdensome means. *See United States ex rel. Donald R. Galmines, et al. v. Novartis Pharmaceuticals Corp.* No. 06-3213, 2015 WL 4973626, at \*2 (citing *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Products Liab. Litig.*, No. 2:13-MD-02436, 2014 WL 3035791, at \*3 (E.D. Pa. July 1, 2014)).

### III. ARGUMENT

As Chief Quality Officer of Aurobindo, Dr. Rao is certainly a high-level official at the “apex” of Aurobindo. Generally, “courts will not allow an apex deposition if the high-ranking official does not have first-hand knowledge of relevant information **or if there are others equally well (or better) situated to provide such information.**” *British Telecomms. PLC v. IAC/InterActiveCorp*, No. 18-366—WCB, 2020 WL 1043974, at \*25 citing *Patterson v. Avery Dennison Corp.*, 281 F.3d 676, 681-82 (7th Cir. 2002), *Thomas v. Int'l Business Machines*, 48 F.3d 478, 482-84 (10th Cir. 1995), and *Reif v. CNA*, 248 F.R.D. 448, 451-55 (E.D. Pa. 2008) (emphasis added).

In their Opposition, Plaintiffs focus on the first prong of the apex doctrine and seem to forget about the second – whether the information sought can be obtained from lower-level employees or through less burdensome means. Even if Dr. Rao had direct knowledge of the material issues in this case, any information that could be obtained from his deposition or from his custodial file can be obtained from the depositions that have already been scheduled and the files that have already been produced or agreed to be produced. Plaintiffs state that Dr. Rao “did much

of this work himself" [Dkt. 1043 p. 7.], but the documents they rely on do not support that statement. None of the 12 documents included as exhibits to Plaintiffs' Opposition indicate that Dr. Rao acted alone or that no lower-level employee has the same knowledge and information.

As laid out in the initial Brief supporting its Motion for Protective Order, the Aurobindo Defendants have provided or are in the process of providing 33 custodial files and have agreed to produce 8 individuals for depositions. One such deposition has since taken place. The remaining custodians that are currently scheduled to sit for depositions include Steve Lucas, Aurobindo's Director of Quality Assurance and Technical Services, and Blessy John, the Director of Regulatory Affairs for APUSA, both of which had contact with the FDA and were involved in the recall. Further, one of the custodial files already produced to Plaintiffs is from Mahesh Shinde, who is also listed as an attendee at the phone conferences and is mentioned in several of the exhibits Plaintiffs rely on to support their position. [See Dkt. 1043-6, 1043-8, 1043-9.] The parties have also agreed upon Mr. Mallikharjun as a custodian, who, along with Mr. Shinde, is also listed as an attendee at the same meetings as Dr. Rao. [See Dkt. 1043-10, 1043-11, 1043-12.] Finally, Aurobindo has proposed Mr. Kesava Reddy and Mr. Nagaraju to testify as to the Lantech topics referenced above. There is no legitimate reason to compel Dr. Rao's deposition and custodial file when these individuals, and others, possess the same knowledge and information about the material issues in this case.

It is clearly more convenient and less burdensome for Plaintiffs to obtain the information they seek from these sources, rather than to force Aurobindo to produce yet another custodial file and schedule another deposition, especially of a high-ranking official such as Dr. Rao. Granting Plaintiffs' request will only serve to delay litigation and cause Aurobindo to incur the added time, expense, and resources to collect and review Dr. Rao's file. Plaintiffs have not attempted to

ascertain what knowledge the other custodians possess or what information their files contain. As a result, they cannot substantiate their allegations that Dr. Rao's testimony is necessary. Therefore, and for all of the foregoing reasons, Plaintiffs' request for Dr. Rao's deposition and custodial file should be denied.

#### **IV. CONCLUSION**

Dr. Rao is an apex witness and granting Plaintiffs' untimely and improper request to depose him and obtain his custodial file would create an undue burden on Aurobindo and Dr. Rao that clearly outweighs any potential benefit to Plaintiffs. Even the documents Plaintiffs themselves rely on to support their position indicate that whatever information they seek from Dr. Rao can be acquired from the custodians Aurobindo has already agreed to produce. Plaintiffs have failed to show that requiring Dr. Rao's testimony and production of his file would be anything but expensive, unduly burdensome, and unnecessarily duplicative. As a result, Aurobindo respectfully requests that this Court grant its Motion for Protective Order and preclude Plaintiffs from deposing Dr. Rao and from obtaining his custodial file.

Respectfully submitted,



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Date: March 23, 2021

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**CERTIFICATE OF SERVICE**

I, Jessica M. Heinz, Esquire, hereby certify that on the below date copies of the foregoing Reply Brief Supporting Aurobindo's Motion for Protective Order Regarding the Deposition of Dr. Ram Mohan Rao and Production of his Custodial File and supporting documents have been served via ECF upon counsel for Plaintiffs and all counsel of record in the Court's electronic filing system.



Date: March 23, 2021

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